

Appl. No. : 09/935,316
Filed : August 22, 2001

AMENDMENTS TO THE CLAIMS

1-29. (Canceled)

30. (Currently Amended) A method for enhancing intestinal absorption of a drug in an animal, said method comprising administering to the animal:

(a) a first population of carrier particles comprising a drug, a carrier particle-forming substance and a bioadhesive material; and

(b) a second population of carrier particles comprising a penetration enhancer;

wherein intestinal tissue is activated by said penetration enhancer prior to the arrival of said drug;

wherein said first population and second population of carrier particles are administered in a single ~~pharmaceutical formulation~~ unit dosage form; and

wherein said ~~pharmaceutical formulation~~ unit dosage form is prepared by preparing said first population of carrier particles, preparing said second population of carrier particles, and combining said first population of carrier particles with said second population of carrier particles in said unit dosage form.

31. (Previously Presented) The method of claim 30 wherein said first population is prepared as a tablet or multiparticulate formulation.

32. (Previously Presented) The method of claim 30 wherein said second population is prepared as a tablet, multiparticulate, emulsion, microemulsion or self-emulsifying system.

33. (Previously Presented) The method of claim 30, wherein said drug is selected from the group consisting of protein, peptide, nucleic acid, oligonucleotide, peptide hormone, antibiotic, antimicrobial agent, vasoconstrictor, cardiovascular drug, vasodilator, enzyme, bone metabolism controlling agent, antihistamine, antitussive, expectorant, chemotherapeutic agent, sedative, antidepressant, beta-blocker, analgesic and angiotensin converting enzyme (ACE) inhibitor.

34. (Previously Presented) The method of claim 30, wherein said penetration enhancer is selected from the group consisting of fatty acid, bile salt, chelating agent and non-chelating surfactant.

35. (Previously Presented) The method of claim 30, wherein said bioadhesive material is selected from the group consisting of polyacrylic polymers, poly(acrylic acid),

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tragacanth, cellulose, polyethyleneoxide cellulose derivatives, kary gum, starch, gelatin pectin, latex, chiostatin, sodium alginate and receptor-binding peptide.

36. (Previously Presented) The method of claim 33, wherein said oligonucleotide is an antisense oligonucleotide.

37. (Previously Presented) The method of claim 33 wherein said oligonucleotide comprises SEQ ID NO:1.

38. (Previously Presented) The method of claim 35 wherein said bioadhesive material comprises a polyacrylic polymer.

39. (Previously Presented) The method of claim 35 wherein said bioadhesive material further comprises hydroxypropylmethylcellulose.

40. (Currently Amended) The method of claim 30, A method for enhancing intestinal absorption of a drug in an animal, said method comprising administering to the animal:

~~(a) a first population of carrier particles comprising a drug, a carrier particle-forming substance and a bioadhesive material; and~~

~~(b) a second population of carrier particles comprising a penetration enhancer; wherein intestinal tissue is activated by said penetration enhancer prior to the arrival of said drug;~~

~~wherein said first population and second population of carrier particles are administered in a single pharmaceutical formulation;~~

~~wherein said pharmaceutical formulation is prepared by preparing said first population of carrier particles, preparing said second population of carrier particles, and combining said first population of carrier particles with said second population of carrier particles; and~~

~~wherein said first population and second population of carrier particles are released concurrently to said intestinal tissue.~~

41. (Currently Amended) The method of claim 30 wherein said ~~formulation-dosage~~ form is not a multicompartment capsule.

42. (Currently Amended) The method of claim 40 wherein said ~~formulation-dosage~~ form is not a multicompartment capsule.

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43. (Currently Amended) The method of claim 30, ~~wherein said first population of carrier particles and said second population of carrier particles are present in a unit dosage form,~~ wherein preparation of said unit dosage form comprises:

preparing a first population of carrier particles by combining drug particles comprising said drug and said carrier particle-forming substance with said bioadhesive material to form said first population of carrier particles;

preparing a second population of carrier particles comprising a penetration enhancer; and

~~mixing~~ combining said first population of carrier particles and said second population of carrier particles to form a single pharmaceutical formulation that is used to make said unit dosage form.

44. (Previously Presented) The method of claim 43, wherein said second population of carrier particles further comprises an enteric coating.

45. (Previously Presented) The method of claim 43, wherein said first population of carrier particles and said second population of carrier particles are mixed with a carrier or excipient.

46. (Previously Presented) The method of claim 43, wherein said unit dosage form is a tablet.

47. (Previously Presented) The method of claim 43, wherein said unit dosage form is a capsule.

48. (Previously Presented) The method of claim 47, wherein said capsule is a single compartment capsule.

49. (Previously Presented) The method of claim 43, wherein said first population of carrier particles and said second population of carrier particles are released from said unit dosage form concurrently.

50. (Currently Amended) The method of claim 40, ~~wherein said first population of carrier particles and said second population of carrier particles are present in a unit dosage,~~ wherein preparation of said unit dosage form comprises:

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preparing a first population of carrier particles by combining drug particles comprising said drug and said carrier particle-forming substance with said bioadhesive material to form said first population of carrier particles;

preparing a second population of carrier particles comprising a penetration enhancer; and

~~mixing~~ combining said first population of carrier particles and said second population of carrier particles to form a single pharmaceutical formulation that is used to make said unit dosage form.

51. (Previously Presented) The method of claim 50, wherein said first population of carrier particles and said second population of carrier particles are mixed with a carrier or excipient.

52. (Previously Presented) The method of claim 50, wherein said unit dosage form is a tablet.

53. (Previously Presented) The method of claim 50, wherein said unit dosage form is a capsule.

54. (Previously Presented) The method of claim 53, wherein said capsule is a single compartment capsule.

55. (Previously Presented) The method of claim 50, wherein said second population of carrier particles further comprises an enteric coating.

56. (Previously Presented) A method for enhancing intestinal absorption of a drug in an animal, said method comprising administering to the animal a unit dosage form containing a pharmaceutical formulation, said formulation comprising:

(a) a first population of carrier particles comprising a drug and a bioadhesive material; and

(b) a second population of carrier particles comprising a penetration enhancer;

wherein said pharmaceutical formulation is prepared by preparing said first population of carrier particles by combining said drug and said bioadhesive material, preparing said second population of carrier particles, and combining said first population of carrier particles with said second population of carrier particles; and

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wherein intestinal tissue is activated by said penetration enhancer prior to the arrival of said drug.

57. (New) The method of claim 56, wherein said drug is an antisense oligonucleotide.

58. (New) The method of claim 30, wherein said method further comprises administering an additional population of carrier particles comprising a penetration enhancer, wherein said additional population of carrier particles comprise a delayed release coating or matrix configured such that dissolution of said additional population of carrier particles is delayed until reaching a location in the intestine downstream from where the drug and penetration enhancer are released from the first population of carrier particles, wherein said additional population of carrier particles are administered in said unit dosage form.